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09/648,196	08/25/2000	Myung-Jin Kim	3066/FLK	5328

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EXAMINER

FOLEY, SHANON A

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 12/05/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/648,196

Applicant(s)

KIM ET AL.

Examiner

Shanon A. Foley

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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### DETAILED ACTION

Applicant has amended claims 1-12 and added new claims 21 and 22.

#### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 7, 10-18, and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by Maniar et al. (WO 92/14449) for reasons of record.

Applicant argues that the teachings of Maniar et al. do not anticipate the instant claims because the fatty acid in the Maniar et al. patent is a microparticle carrier for a peptide and the lipophilic substance of the instant invention is used to coat a solid microparticle to improve dispensability and in vivo adsorption rate.

Applicant arguments have been considered, but are found to be unpersuasive because the claims are drawn to a solid lipophilic microparticle comprising a lipophilic substance and an active ingredient, where the microparticle has been coated with a lipophilic substance. Maniar et al. teaches a protein is dissolved into a solvent and formed into a desired particle size and then mixed with a fatty acid, see the last paragraph on page 6. Therefore, Maniar et al. anticipates all of the elements in the claims, i.e. a microparticle that comprises a protein and a lipophilic substance, where the microparticle has been coated with a lipophilic substance.

Claims 1-6, 8-12, 15, and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Poli et al. (5,759,566) for reasons of record.

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Applicant argues that the active ingredient is not encased in the lipophilic microparticles. Applicant further summarizes the examples of Poli et al. and argues that Poli et al. does not teach an antigen encased in a solid microparticle coated only on its surface a lipophilic substance.

Applicant's arguments, as well as a review of Poli have been considered, but are found to be unpersuasive. Poli et al. teaches a protein dissolved into a solvent and formed into a desired particle size and then mixed with a fatty acid anticipates all of the elements in the claims, i.e. a microparticle that comprises a protein and a lipophilic substance, where the microparticle has been coated with a lipophilic substance.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Poli et al. for reasons of record.

Applicant based arguments to this rejection in the previous section, which were found to be unpersuasive, as discussed above.

Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Poli et al. or Maniar et al. as applied to claims 1-21 above, and further in view of Chen et al. (Journal of Virology. 1998; 72 (7): 5757-5761.

The claim is drawn to the microparticle antigen a nucleic acid.

See the teachings of Poli et al. or Maniar et al. above. Neither reference teaches that the antigen is a nucleic acid.

However, Chen et al. teaches a rotavirus VP6 DNA vaccine encapsulated in microparticles that resulted in protective immunity against subsequent rotavirus challenge. One of ordinary skill in the art at the time the invention was made would have been motivated to incorporate DNA as an antigen into the microparticles of Poli et al. or Maniar et al. because the DNA is taken up by host cells and present the normally processed proteins to the immune system that raise specific immune responses to the native forms of the proteins, see Chen et al. in the first column. One of ordinary skill in the art at the time the invention was made also would have been motivated to incorporate the DNA microparticle of Chen et al. into the lipophilic capsule of Poli et al. or Maniar et al. to control the amount and duration of DNA to be released, see the second paragraph of Maniar et al., and ensure bioadhesive capabilities to increase the amount of absorption while extending the amount of time the microparticle remains in the system, see Poli et al. column 2, lines 5-20. One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success producing the claimed invention because the lyophilized microparticles containing DNA of Chen et al. (see the second and third paragraphs of column 1 on page 5758) would dissolve into the lipophilic solvent of Poli et al. (columns 5 and 6). In addition, the ordinary artisan would be able to substitute the lyophilized particle of Chen et al. for the powdered protein of Maniar et al. into the lipophilic microparticulate carrier (see page 7 of Maniar et al. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made.

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***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon A. Foley whose telephone number is (703) 308-3983.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Shanon Foley/SAF  
November 21, 2001

  
JAMES HOUSEL 12/3/01  
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